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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,443	08/30/2001	Jean-Christophe Audonnet	454313-2220.1	9956

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,443	AUDONNET ET AL.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-25* is/are pending in the application.

4a) Of the above claim(s) *11-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-25* is/are rejected.

7)☒ Claim(s) *24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/232,278.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *August 30, 2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group II, claims 21-25 in the reply filed on August 16, 2004 is acknowledged. The traversal is on the ground(s) that the Office failed to establish burden of search. This is not found persuasive because, as previously indicated in the Restriction Requirement of June 15, 2004, page 2, the Office demonstrated that the Groups are separately classified and indicated that conducting a separate literature search for Groups I and II would be burdensome. Indeed, such a search would be a serious burden for the above-stated reasons. Applicant also argues that a search for Group II will necessarily be co-extensive for Group I. In response, a search for the product of Group I will extend beyond its method of use. For example, searching the product's use in a method of immunization will not necessarily reveal prior art on the product itself, which may have existed prior to the disclosure of use as an immunogen. Applicant was advised in the Restriction requirement that the election of product claims, if found allowable, would entitle Applicant to rejoinder of the method claims related to the product. However, in this instance, Applicant has elected a method claim and therefore, the rejoinder of the product should the method be found allowable, is not a matter of right. The requirement is still deemed proper and is therefore made FINAL. Claims 11-25 are pending. Claims 11-20 are withdrawn from consideration, being drawn to a non-elected invention. Claims 21-25 are under examination.

Claim Objections

2. Claim 24 is objected to for a minor informality. Claim 24 recites, "cytomeglovirus early (CMV-IE) promoter". Cytomegalovirus is misspelled. Also, the acronym and the spelling-out

of the acronym do not match. If Applicant intends to claim CMV-IE, then it should be spelled out as "cytomegalovirus immediate early (CMV-IE) promoter". Correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inducing in a feline host an immunological response against feline immunodeficiency virus (FIV) comprising at least one plasmid in a feline $CD4^+$ or $CD8^+$ T-cells, does not reasonably provide enablement for the use of any feline host cell for expression of FIV. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The breadth of the claims is unreasonable, encompassing the expression of FIV nucleic acid in any feline host cell. The nature of the invention is the expression of foreign nucleic acid from an immunodeficiency virus in a host cell. The state of the art shows that FIV and its proteins only infect or are expressed in feline $CD4^+$ or $CD8^+$ T-cells (Choi *et al.*, *J. Virology*, 2000, 74(2):676-683, particularly page 676, first column, first paragraph). The level of one of ordinary skill and the level of predictability in the art is high with regard to knowing the cell types that are susceptible to FIV infection. The amount of direction, guidance and working examples in the specification are silent on the types of feline host cells that express the plasmid. Given the breadth of the claims, the state of the art, the level

of skill in the art, the level of predictability in the art and the lack of guidance/working examples in the specification, the claims are not enabled for their full scope. The claims are enabled only for feline host cells that are $CD4^+$ or $CD8^+$ T-cells.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. It is unclear how to perform the claimed invention without method steps. The claims are simply drawn to a method for inducing an immune response, followed by the components with which to induce the immune response. However, there are no steps to show how to induce the immune response. Is the plasmid administered alone? Is the plasmid introduced into the feline host cell and then the host cell is administered to the feline for immunization? The claims as written only indicate that the plasmid can express a nucleic acid in a host cell. Clarification and correction regarding the missing method steps are required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 21, 24 and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Wardley *et al.* (WO95/30019, herein, "Wardley"). The claims are drawn to a method for inducing in a feline host an immunological response against feline immunodeficiency virus comprising at least one plasmid that contains and expresses in vivo in a feline host cell nucleic acid molecules having sequences encoding feline immunodeficiency virus env protein, or gag protein, or pro protein, or gag and pro proteins, or env and gag and pro proteins. The method further comprises administering a live whole vaccine against a feline pathogen, or an inactivated whole vaccine against a feline pathogen, or recombinant vaccine against a feline pathogen, or a subunit vaccine against a feline pathogen. The plasmid further comprises a cytomegalovirus early promoter. (Since the claims do not recite method steps, the claims have been broadly interpreted to be any method of inducing an immune response that uses a plasmid encoding the appropriate FIV genes.)

Wardley teaches a method of inducing an immune response in felines by administering a recombinant feline herpes virus vector containing DNA encoding FIV gag and env proteins (Wardley, abstract and claim 11). The FIV DNA of env and gag are inserted into transfer vectors/plasmids, and CMV early promoter is used (pages 7-8, bridging paragraph, and page 13, lines 22-23). Therefore, the claims are anticipated by Wardley.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardley as applied to claims 21, 24 and 25 above, and further in view of Mazzara *et al.* (U.S. Patent 5,804,196, herein, "Mazzara"). The claims are drawn to a method for inducing in a feline host an immunological response against feline immunodeficiency virus comprising at least one plasmid that contains and expresses in vivo in a feline host cell nucleic acid molecules having sequences encoding feline immunodeficiency virus env protein, or gag protein, or pro protein, or gag and pro proteins, or env and gag and pro proteins. The method further comprises administering a live whole vaccine against a feline pathogen, or an inactivated whole vaccine against a feline pathogen, or recombinant vaccine against a feline pathogen, or a subunit vaccine against a feline pathogen. The teachings of Wardley are summarized above. Wardley is silent on the use of the protease (pro) gene of FIV.

However, Mazzara discloses a recombinant fowlpox viral vector that expresses the env, gag and pol genes of lentiviruses such as HIV, FIV or SIV (col. 3, lines 37-46). Mazzara also teaches that the vector can be administered with live recombinant viruses (col. 8, lines 45-50). It would have been obvious to incorporate the pol gene, which contains the pro gene, into Wardley's vector because pol protein (pro protein) is capable of eliciting an immune response (col. 8, lines 39-44). One would have had a reasonable expectation of success that a vector that

contains env, gag and pol (pro) would have induced an immune response, because Mazzara's vector contains env, gag and pol (pro) and elicits an immune response. It would have also been obvious to administer Wardley's vector with a live recombinant virus because Mazzara teaches the co-administration of the vector and live recombinant virus for a total vaccination protocol (col. 8, lines 45-50). One would have had a reasonable expectation of success that the administration of both the vector and a live recombinant virus would have induced an immune response because both elements are separately capable of inducing an immune response. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

8. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

SBC
Stacy B. Chen
September 28, 2004

James C. Housel 10/1/04
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